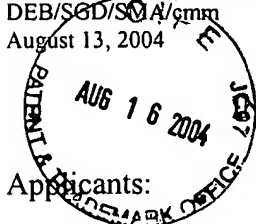


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THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Stavros C. Manolagas, Robert L. Jilka, Robert S. Weinstein and Teresita Bellido

Application No.: 10/730,751 Group Art Unit: 1632

Filed: December 8, 2003 Examiner: Not Assigned

Confirmation No.: 4492

Title: IN VITRO AND IN VIVO MODELS FOR SCREENING COMPOUNDS TO PREVENT GLUCOCORTICOID-INDUCED BONE DESTRUCTION

CERTIFICATE OF MAILING OR TRANSMISSION	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, or is being facsimile transmitted to the United States Patent and Trademark Office on:	
8/13/04	<i>Christina M. Sweeney</i>
Date	Signature
<i>Christina M. Sweeney</i>	
Typed or printed name of person signing certificate	

INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted:

☐ under 37 CFR 1.129(a), or  
(First/Second submission after Final Rejection)

☒ under 37 CFR 1.97(b), or  
(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).

☐ under 37 CFR 1.97(c) together with either:  
☐ a Statement under 37 CFR 1.97(e), as checked below, or  
☐ a \$180.00 fee under 37 CFR 1.17(p), or  
(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)

☐ under 37 CFR 1.97(d) together with:  
☐ a Statement under 37 CFR 1.97(e), as checked below, and  
☐ a \$180.00 fee under 37 CFR 1.17(p), or  
(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)

☐ under 37 CFR 1.97(i):  
Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.  
(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.

☒ Enclosed herewith is form PTO-1449:

- ☐ Copies of the cited references are enclosed.

☒ Since this application was filed after June 30, 2003, copies of issued U.S. patents and published U.S. applications are not required and are not being provided.

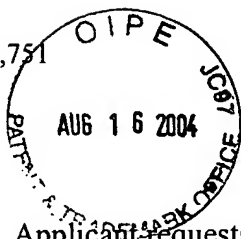
- ☒ Copies of the cited references are enclosed except those entered in prior application, U.S. Application No. 09/413,958, to which priority under 35 U.S.C. 120 is claimed. The earlier application contains copies of the cited references.

**It is noted that the Reference Nos. assigned to the cited documents on the PTO-1449 Form being filed herewith are different from the Reference Nos. in the prior application. It is believed that the other identifying information found in the 1449 should be sufficient to permit consideration of the cited documents by the Examiner. If the Examiner would like additional copies of all references, it is requested that the undersigned be notified.**

- ☐ The listed references were cited in the enclosed International Search Report in a counterpart foreign application.

- ☐ The "concise explanation" requirement (non-English references) for reference(s) [ ] under 37 CFR 1.98(a)(3) is satisfied by:

- ☐ the explanation provided on the attached sheet.
- ☐ the explanation provided in the Specification.
- ☐ submission of the enclosed International Search Report.
- ☐ submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
- ☐ the enclosed English language abstract.



☐ Applicant requests that the following non-published pending applications be considered:

Examiner's  
Initials

\_\_\_\_ U.S. Patent Application No. [ ], by [inventor(s)], filed [ ], Docket No.: [ ]  
\_\_\_\_ U.S. Patent Application No. [ ], by [inventor(s)], filed [ ], Docket No.: [ ]  
\_\_\_\_ U.S. Patent Application No. [ ], by [inventor(s)], filed [ ], Docket No.: [ ]

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Examiner

\_\_\_\_\_  
Date

- ☐ A copy of each above-cited application, including the current claims, is enclosed.
- ☐ A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [ ], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

- ☐ A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.
- ☐ Please charge Deposit Account 08-0380 in the amount of \$[ ]. A copy of this Statement is enclosed.
- ☒ Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

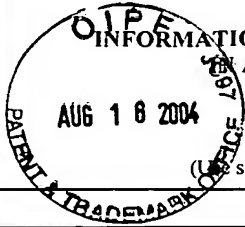
Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By Susan M. Abelleira  
Susan M. Abelleira  
Registration No.: 42,252  
Telephone: (978) 341-0036  
Facsimile: (978) 341-0136

Concord, MA 01742-9133

Dated: August 13, 2004

PTO-1449 REPRODUCED		ATTORNEY DOCKET NO. 3650.1003-007		APPLICATION NO. 10/730,751	
		FIRST NAMED INVENTOR Stavros C. Manolagas		FILING DATE December 8, 2003	
		EXAMINER Not Assigned		CONFIRMATION NO. 4492	
				GROUP 1632	

## U.S. PATENT DOCUMENTS

EXAM- INER INI- TIAL	REF. NO.	DOCUMENT NUMBER Number-Kind Code (if known)	ISSUE DATE / PUBLICATION DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT
	AA	5,071,773	12/10/1991	Evans, <i>et al.</i>
	AB	5,189,212	02/23/1993	Ruenitz
	AC	5,298,429	03/29/1994	Evans, <i>et al.</i>
	AD	5,362,720	11/08/1994	Labrie
	AE	5,506,102	04/09/1996	McDonnell
	AI	5,545,634	08/13/1996	Labrie
	AG	5,554,601	09/10/1996	Simpkins, <i>et al.</i>
	AH	5,567,695	10/22/1996	Labrie
	AI	5,843,934	12/01/1998	Simpkins, <i>et al.</i>
	AJ	5,846,960	12/10/1998	Labrie
	AK2	5,877,007	03/02/1999	Housey
	AA2	6,080,779	06/27/2000	Gasper, <i>et al.</i>
	AB2	US 20020137209	09/26/2002	Manolagas, <i>et al.</i>
	AC2			
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## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER Country Code-Number-Kind Code (if known)	DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT	TRANSLATION YES NO	
	AL	EP 0 753 523 A1	01/15/1997	Gador S.A.		
	AM	WO 99/54728 A2	10/28/1999	Novalon Pharmaceuticals Corp.		
	AP	WO 99/61044 A1	12/02/1999	The Board of Trustees of the University of Arkansas		
	AO	WO 00/19823 A1	04/13/2000	The Board of Trustees of the University of Arkansas		
	AP	WO 00/20007 A1	04/13/2000	The Board of Trustees of the University of Arkansas		
	AQ	WO 00/20625 A1	04/13/2000	The Board of Trustees of the University of Arkansas		
	AL2	WO 00/37681 A1	06/29/2000	American Home Products Corporation		
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## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

AR	Aarden, E.M., <i>et al.</i> , "Function of Osteocytes in Bone", <i>J. Cell. Biochem.</i> , 55:287-299 (1994).
AS	Bellido, <i>et al.</i> , "PTH Prevents Glucocorticoid Apoptosis of Osteoblasts and Osteocytes In Vitro: Direct Interference with a private Death Pahtyway Upstream of Caspase-3", <i>Abstract. Bone.</i> , 23:S324 (1998).
AT	Dunstan, <i>et al.</i> , "Osteocyte Death and Hip Fracture", <i>Clacif Tissue Int.</i> , 53: Supp11: S113-S117 (1993).
AU	Falcini, F., <i>et al.</i> , "Intravenous Administration of Alendronate Counteracts the In Vivo Effects of Glucocorticoids on Bone Remodeling", <i>Calcified Tissue International.</i> , 58:166-169 (1996).
AV	Felson, <i>et al.</i> , "Across-Study Evaluation of Association between Steroid Dose and Bolus Steroids and Avascular Necrosis of Bone", <i>The Lancet April</i> , 18:902-905 (1987).
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AX	Kato, Y., <i>et al.</i> , "Establishment of an Osteocyte- like Cell Line, MLO-Y4", <i>J. Bone Miser. Res.</i> , 12:2014-2023 (1997).
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AZ	Noble, <i>et al.</i> , "Identification of Apoptotic Changes in Osteocytes in Normal and Pathologic Human Bone", <i>Bone</i> , 20:273-282 (1997).
AR2	Reid, I.R., <i>et al.</i> , "Prevention of Glucocorticoid-Induced Osteoporosis", <i>Journal of Bone and Mineral Research</i> , 5:619-623 (1990).
AS2	Schwartz, B.D., <i>et al.</i> , "Differential Regulation of Prostaglandin E <sub>2</sub> Synthesis and Phospholipase A <sub>2</sub> Activity by 1,25-(OH) <sub>2</sub> D <sub>3</sub> in Three Osteoblast-like cell lines", <i>Bone</i> , 13:51-58 (1992).
AT2	Weinstein, R.S., <i>et al.</i> , "Inhibition of Osteoblastogenesis and Promotion of Apoptosis of Osteoblasts and Osteocytes by Glucocorticoids", <i>The Journal of Clinical Investigation</i> , 102:274-282 (1998).
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**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

AV2	Bellows, C.G., <i>et al.</i> , "Physiological Concentrations of Glucocorticoids Stimulate Formation of Bone Nodules from Isolated Rat Calvaria Cells in <i>Vitro</i> ", <i>Endocrinology</i> , 121:4-6:1985-1992 (1987).
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AX2	Bressot, C., <i>et al.</i> , "Histomorphometric Profile, Pathophysiology, and Reversibility of Corticosteroid-induced Osteoporosis", <i>Metabolic Bone Disease &amp; Related Research</i> , 1:303-311 (1979).
AY2	Broulik, Ph.D., <i>et al.</i> , "Effect of Antiandrogens Casodex and Epi-testosterone on Bone Composition in Mice", <i>Bone</i> , 20:473-475 (1997).
AZ2	Bursch, W., <i>et al.</i> , "Determination of the length of the histological stages of apoptosis in normal liver and in altered hepatic foci of rats", <i>Carcinogenesis</i> , 11:847-853 (1990).
AR3	Chavassieux, P., <i>et al.</i> , "Short-Term Effects of Corticosteroids on Trabecular Bone Remodeling in Old Ewes", <i>Bone</i> , 20:451-455 (1997).
AS3	Conaway, H.H., <i>et al.</i> , "Stimulation of Neonatal Mouse Calvarial Bone Resorption by the Glucocorticoids Hydrocortisone and Dexamethasone", <i>Journal of Bone and Mineral Research</i> , 11:1419-1429 (1996).
AT3	Cline, M.J., "Drugs and Phagocytes", <i>The New England Journal of Medicine</i> , 291:1187-1188 (1974).
AU3	Cope, C.L., "Synthetic Analogues", <i>Adrenal Steroids and Disease</i> , Lippincott, PA, USA, 488-491 (1972).
AV3	Cushing, H., "The Basophil Adenomas of the Pituitary Body and their Clinical Manifestations", <i>Bulletin of the John Hopkins Hospital</i> , 1:137-195 (1932).
AW3	Deloffre, P., <i>et al.</i> , "Comparison Between Bone Density and Bone Strength in Glucocorticoid-Treated Aged Ewes", <i>Bone</i> , 17(Suppl):409S-14S (1995).
AX3	Dempster, D.W., "Bone Histomorphometry in Glucocorticoid-Induced Osteoporosis", <i>Journal of Bone and Mineral Research</i> , 4:137-141 (1989).
AY3	Dempster, D.W., <i>et al.</i> , "Glucocorticoids Inhibit Bone Resorption by Isolated Rat Osteoclasts by Enhancing Apoptosis", <i>Journal of Endocrinology</i> , 154:397-406 (1997).

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**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

AZ3	Falla, N., <i>et al.</i> , "Characterization of a 5-Fluorouracil-Enriched Osteoprogenitor Population of the Murine Bone Marrow", <i>The Journal of The American Society of Hematology</i> , 82:3580-3591 (1993).
AR4	Fitzpatrick, L.A., "Glucocorticoid-Induced Osteoporosis", <i>Osteoporosis</i> , 202-226 (1994).
AS4	Frey, F.J., "Kinetics and Dynamics of Prednisolone", <i>Endocrine Reviews</i> , 8:453-473 (1987).
AT4	Frost, H.M., "In Vivo Osteocyte Death", <i>The Journal of Bone and Joint Surgery</i> , 42-A:1-8:138-150 (1960).
AU4	Gohel, A., <i>et al.</i> , "Glucocorticoids Induce Apoptosis in Osteoblasts by the Regulation of BCL-2, BAX and Other Cell Cycle Factors", <i>Journal of Bone and Mineral Research</i> , Abstract, F234:S284 (1997).
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AX4	Jilka, R.L., <i>et al.</i> , "Osteoblast Programmed Cell Death (Apoptosis): Modulation by Growth Factors and Cytokines", <i>J. of Bone and Mineral Research</i> , 13:793-802 (1998).
AY4	Jilka, R.L., <i>et al.</i> , "Increased Osteoclast Development After Estrogen Loss: Mediation by Interleukin-6", <i>Science</i> , 257:88-91 (1992).
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AR5	King, C.S., <i>et al.</i> , "Effects of Continuous Glucocorticoid Infusion on Bone Metabolism in the Rat", <i>Calcified Tissue International</i> , 59:184-191 (1996).
AS5	Kleiber, M., "The Fire of Life: An Introduction to Animal Energetics", John Wiley & Sons, Inc., New York Chapter, 10:177-216 and 11:217-230 (1961).
AT5	Klein, M., <i>et al.</i> , "A Quantitative Histological Study of Rib From 18 Patients Treated with Adrenal Cortical Steroids", <i>Acta Orthopaedica Scandinavica</i> , XXXV:171-184 (1965).

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				GROUP 1632	

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

AU5	Knight, B., <i>et al.</i> , "Induction of Adjuvant Arthritis in Mice", <i>Clinical and Experimental Immunology</i> , 90:459-465 (1992).
AV5	Li, M., <i>et al.</i> , <i>Bone</i> 19:81-88 (1996).
AW5	Lian, J.B., <i>et al.</i> , "Species-Specific Glucocorticoid and 1,25-Dihydroxyvitamin D Responsiveness in Mouse MC3T3-E1 Osteoblasts: Dexamethasone Inhibits Osteoblast Differentiation and Vitamin D Down-Regulates Osteocalcin Gene Expression", <i>Endocrinology</i> , 138:2117-2127 (1997).
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AY5	Lynch, M.P., <i>et al.</i> , "Apoptosis During Bone-Like Tissue Development in Vitro", <i>Journal of Cellular Biochemistry</i> , 68:31-49 (1997).
AZ5	Mankin, H.J. "Nontraumatic Necrosis of Bone (Osteonecrosis)", <i>The New England Journal of Medicine</i> , 326:1473-1479 (1992).
AR6	Newman, E., <i>et al.</i> , "The Potential of Sheep for the Study of Osteopenia: Current Status and Comparison with Other Animal Models", <i>Bone</i> , 16:277-284S (1995).
AS6	Owen, M., "Lineage of Osteogenic Cells and Their Relationship to the Stromal System", <i>Bone and Mineral Research</i> /3, 1-25 (1985).
AT6	Parfitt, A.M., "Osteonal and Hemi-Osteonal Remodeling: The Spatial and Temporal Framework for Signal Traffic in Adult Human Bone", <i>Journal of Cellular Biochemistry</i> , 55:273-286 (1994).
AU6	Parfitt, A.M., <i>et al.</i> , "Bone Histomorphometry: Standardization of Nomenclature, Symbols, and Units", <i>Journal of Bone and Mineral Research</i> , 2:595-610 (1987).
AV6	Parfitt, A.M., "Bone-Forming Cells in Clinical Conditions", <i>Bone</i> , Vol. 1, The osteoblast and osteocyte, 351-430, CRC Press, Boca Raton (1996).
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				GROUP 1632	

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

AY6	Quarles, L.D., "Prednisone-Induced Osteopenia in Beagles: Variable Effects Mediated by Differential Suppression of Bone Formation", <i>American Journal of Physiology</i> , 263:E136-E141 (1992).
AZ6	Reid, I.R., "Pathogenesis and Treatment of Steroid Osteoporosis", <i>Clinical Endocrinology</i> , 30:83-103 (1989).
AR7	Stanton, B., <i>et al.</i> , "Effects of Adrenalectomy and Chronic Adrenal corticosteroid Replacement on Potassium Transport in Rat Kidney", <i>The Journal of Clinical Investigation</i> , 75:1317-1326 (1985).
AS7	Tomkinson, A., <i>et al.</i> , "The Death of Osteocytes via Apoptosis Accompanies Estrogen Withdrawal in Human Bone", <i>Journal of Clinical Endocrinology and Metabolism</i> , 82:3128-3135 (1997).
AT7	Weinstein, R.S., <i>et al.</i> , "The Effects of Androgen Deficiency on Murine Bone Remodeling and Bone Mineral Density are Mediated via Cells of the Osteoblastic Lineage", <i>Endocrinology</i> , 138:4013-4021 (1997).
AU7	Weinstein, R.S., <i>et al.</i> , "Diminished Rates of Bone Formation in Normal Black Adults", <i>The New England Journal of Medicine</i> , 319:1698-1701 (1988).
AV7	Giuliani, <i>et al.</i> , "Bisphosphonates stimulate formation of osteoblast precursors and mineralized nodules in murine and human bone marrow cultures in vitro and promote early osteoblastogenesis in young and aged mice in vivo", <i>Bone</i> , 22(5):455-461 (1998).
AW7	Hill, <i>et al.</i> , "Multiple extracellular signals promote osteoblast survival and apoptosis", <i>Endocrinology</i> , 138(9):3849-3858 (1997).
AX7	Jilka, <i>et al.</i> , "Dexamethasone Promotes Apoptosis of Osteoblast Progenitors in Murine Bone Marrow Cultures: Antagonism by IL-6 Type Cytokines", <i>Journal of Bone and Mineral Research</i> , 12(Supp):S455, abstract number S411 (1997).
AY7	Manolagas, <i>et al.</i> , "New Developments in the pathogenesis and treatment of steroid-induced osteoporosis", <i>Journal of Bone and Mineral Research</i> , 14(7):1061-1066 (1999).
AZ7	Rogers, <i>et al.</i> , "Bisphosphonates induce apoptosis in mouse macrophage-like cells in vitro by a nitric oxide-independent mechanism", <i>Journal of Bone and Mineral Research</i> , 11(10):1482-1491 (1996).
AR8	Tomkinson, <i>et al.</i> , "The role of estrogen in the control of rat osteocyte apoptosis", <i>Journal of Bone and Mineral Research</i> , 13(8):1243-1250 (1998).

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PTO-1449 REPRODUCED  <b>INFORMATION DISCLOSURE CITATION IN AN APPLICATION</b>  August 13, 2004 (Use several sheets if necessary)		ATTORNEY DOCKET NO. 3650.1003-007  FIRST NAMED INVENTOR Stavros C. Manolagas  EXAMINER Not Assigned		APPLICATION NO. 10/730,751  FILING DATE December 8, 2003  CONFIRMATION NO. 4492 GROUP 1632	
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**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

	AS8	Weinstein, <i>et al.</i> , "Inhibition of osteoblastogenesis and promotion of apoptosis of osteoblasts and osteocytes by glucocorticoids: potential mechanisms of their deleterious effects on bone", <i>Journal of Clinical Investigation</i> , 102(2):274-282 (1998).
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EXAMINER	DATE CONSIDERED
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